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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/049,366

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EXAMINER

DIRAMIO, JACQUELINE A

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/049,366	<b>Applicant(s)</b> TAKAHASHI ET AL.	
	<b>Examiner</b> JACQUELINE DIRAMIO	<b>Art Unit</b> 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 May 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-9,11,24-27 and 31-36 is/are pending in the application.
- 4a) Of the above claim(s) 5,6,24-27,31-33 and 35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,7-9,11,34 and 36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 May 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of the Claims***

1. Applicant's amendments to claim 1 are acknowledged.
2. Currently, claims 1, 3, 4, 7 – 9, 11, 34 and 36 are pending and under examination.

Claims 5, 6, 24 – 27, 31 – 33, and 35 are acknowledged as withdrawn as drawn to non-elected inventions.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1, 3, 4, 7 – 9, 11, 34 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burd et al. (US 5,939,331) in view of Killeen et al. (US 5,166,051).

Burd et al. teach a test device (biosensor) that is made of plural layers of porous material, said device having a labeling zone 26 (reagent holding part) which holds a labeled reagent for

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analyzing an analyte in a whole blood sample (liquid specimen having cell components contained therein), said device analyzing target components in the sample by utilizing chromatography, said device further comprising:

a matrix 23 (carrier) carrying a cell-binding reagent having the ability of immobilizing cell components of said blood sample on at least a part of an area of said matrix, said area ranging from a sample (specimen) addition part to which the sample is added to a labeling zone 26 thereof; and

a nitrocellulose section 27 (reaction layer) with capture zone 29 chromatographically downstream of said matrix 23 on which a reaction between the analyte in the blood sample and the labeled reagent eluted from the labeling zone is carried out, wherein the nitrocellulose section (reaction layer) comprising the capture zone includes a porous material, i.e. nitrocellulose, that permits penetration of the sample mixed with various other components, including the analyte and the labeled reagent (see Figure 1; column 2, lines 8-62; column 5, lines 6-38; column 8, lines 14-67; column 9, lines 1-67; and column 10, lines 1-14).

However, Burd et al. fail to teach that the matrix includes a cell shrinkage reagent having the ability of making the cell components of said blood sample (liquid specimen) shrink, wherein the shrunk cell components are made smaller by said cell shrinkage reagent.

Killeen et al. teach a diagnostic test strip for chemically determining whole blood analytes comprising a support, a porous detection zone membrane, and an overlay membrane in overlying and continuous contact with the detection zone membrane. A sample of whole blood is applied to the overlay membrane, wherein the overlay membrane contains an effective amount of a crenating agent. The crenating agent functions to deplete the volume of fluid within the red

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blood cells, which shrinks and rigidifies the cells, making them less flexible. The rigidified cells are less able to penetrate into the pores of the detection zone membrane, which allows for the passage of analyte that has been released from the solution of the whole red blood cells into the detection zone membrane (see Abstract; and column 5, lines 5-61).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include with the device of Burd et al. a cell shrinking reagent within the sample addition matrix as taught by Killeen et al. because Killeen et al. teach the benefit of including a crenating (cell shrinking) reagent within a sample addition membrane, i.e. overlay membrane, of a test strip used in determining whole blood analytes because the crenating agent functions to deplete the volume of fluid within the red blood cells of a blood sample, which shrinks and rigidifies the cells, making them less flexible and less able to penetrate into the pores of the detection zone membrane, which allows for the passage of analyte that has been released from the solution of the whole red blood cells into the detection zone membrane.

With respect to Applicant's claim 3, Killeen et al. teach that the liquid specimen, i.e. sample, can include bacteria (see column 6, lines 17-18).

With respect to Applicant's claim 4, Killeen et al. teach that the cell crenating (shrinkage) reagent is an inorganic salt (see column 5, lines 48-61).

With respect to Applicant's claims 7 and 9, Killeen et al. teach that the cell crenating reagent is dried naturally or air-dried with heat (see column 10, lines 34-39).

With respect to Applicant's claim 8, Burd et al. teach that the cell reagent applied to the sample matrix can be dried or lyophilized (freeze-dried) (see column 5, lines 6-12; and Example 1).

With respect to Applicant's claim 11, Burd et al. teach that the test device is a dry analytical element (see Abstract; Figure 1; column 9, lines 57-67; and column 10, lines 1-14).

With respect to Applicant's claim 34, Killeen et al. teach that the crenating reagent, preferably in the form of sodium chloride, should have a concentration from about 0.85 to about 35% (see column 5, lines 64-68; and column 6, lines 1-8).

With respect to Applicant's claim 36, the limitations of this claim are unpatentable over Burd et al. in view of Killeen et al., as discussed above with respect to Applicant's claim 1. Further, Burd et al. teach that the test device is in the form of a one-step immunochromatographic test strip, wherein the liquid sample is whole blood (see Abstract; Figure 1; column 9, lines 57-67; and column 10, lines 1-14).

### ***Response to Arguments***

4. Applicant's arguments filed May 22, 2009 have been fully considered but they are not persuasive. In particular, Applicant argues (see pages 7-11) that the combination of Burd et al. in view of Kileen et al. fails to render obvious Applicant's claimed invention because both devices of Burd et al. and Kileen et al. prevent the passage of red blood cells into the remainder of the device as recited in Applicant's independent claim 1. In addition, Applicant argues that both Burd et al. and Kileen et al. teach away from a "reaction layer that includes a porous material that permits the shrunk cell components to penetrate the reaction layer," and thus, one

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would not be motivated to combine Burd et al. with Killeen et al. in any manner.

However, these arguments are not found persuasive. Although it may be apparent from the references that the Burd et al. and Killeen et al. references are attempting to remove red blood cells from the blood sample applied to their respective devices, it is further apparent that the combination of Burd et al. in view of Killeen et al. provides a device (biosensor) that contains all of the required structural and chemical elements of Applicant's amended independent claim 1. The Burd et al. reference includes all of the structural requirements of Applicant's claimed invention including a "porous material" in the nitrocellulose section (i.e. reaction layer), except for the inclusion of a cell shrinkage reagent (i.e. crenating agent) within the carrier component. Killeen et al. provide a teaching of and motivation for including a crenating reagent within a test strip device, wherein the crenating agent comprises the same compound as recited in Applicant's claimed invention, i.e. an inorganic salt. Therefore, because the combination of Burd et al. in view of Killeen et al. results in the biosensor device of Burd et al. including the crenating agent of Killeen et al., the combination of Burd et al. in view of Killeen et al. contains all of the structural limitations and components of Applicant's claimed invention and provides motivation thereof, and thus renders Applicant's claims unpatentable and obvious. Further, given that Killeen et al. do in fact provide motivation for including a crenating reagent within a device, such as the one taught by Burd et al., it is not considered persuasive that either reference "teaches away" from such a combination.

In addition, Applicant's recited limitation, which requires that the porous material "permits the shrunk cell components to penetrate the reaction layer in a manner that forms a mixed state that comprises the liquid specimen mixed with at least the shrunk cell components,

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the analyte, and the reagent," comprises an intended use limitation, and further provides no other structural requirements except for a porous material. Therefore, because Burd et al. include a porous material in their nitrocellulose section, and because the combination of Burd et al. in view of Killeen et al. contains all other structural and chemical requirements of Applicant's claimed invention, the combination would expectedly function in the same way and therefore would be capable of performing the recited intended use.

### ***Conclusion***

5. No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.



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Any inquiry concerning this communication or earlier communications from the examiner should be directed to JACQUELINE DIRAMIO whose telephone number is (571)272-8785. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jacqueline DiRamio/  
Examiner, Art Unit 1641

/Bao-Thuy L. Nguyen/  
Primary Examiner, Art Unit 1641  
August 10, 2009